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10/555,289	07/03/2006	Jean-Luc Georges Battini	0508-1149	9338

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EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/555,289	BATTINI ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-27 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-27 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/2/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 16- 27, 29, 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response to the previous rejection, applicant has amended claim 16 to include active steps of contacting a sample and determining the level of bound polypeptide. The method is still incomplete, as it does not relate the level of bound polypeptide to the diagnosis of pathologies recited in the claim preamble. In addition, the claim is indefinite in reciting "sequences derived thereof", since an infinite number of sequences can be "derived" from a sequence by insertion, deletion, and substitution.

Claims 16-27, 29, 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for in vitro diagnosis of cells overexpressing GLUT1 on cell surfaces and diagnosing tumors, does not reasonably provide enablement for diagnosing inflammatory conditions, immune or autoimmune disorders, or central nervous system disorders, or preventing or treating pathologies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant argues that cancers can be diagnosed. The examiner agrees. The method as claimed involves a biological sample, and applicant's arguments regarding imaging techniques are not directed to the method as claimed.

Applicant argues that GLUT1 expression is induced by T cell activation, and therefore has been linked to inflammatory conditions. Different inflammatory cells, such as lymphocytes, macrophages, or microglias in a biopsy can be distinguished by aberrantly high GLUT1 expression, and mononuclear cells can be detected by cell sorting. However, this information is absent from the specification, which contains no direction whatsoever as to what cell types to analyze for diagnosis of inflammatory conditions. Therefore, while enabling for the general process of diagnosing cells overexpressing GLUT1 on cell surfaces, the specification does not teach the artisan where to look for overexpression in order to diagnose all of the disease conditions recited in the claims.

In regard to prevention or treatment, applicant argues that glucose transportation can be inhibited by peptide binding. The examiner agrees. What is missing is evidence that the inhibition of glucose transportation has a beneficial therapeutic effect upon the disease conditions recited in the claims. Applicant argues that the peptides could conceivably be used as an antiviral agent. However, for effective use as an antiviral agent, the specification does not teach how to overcome the pharmacological problems of providing the peptide in effective concentrations at the appropriate target site, while avoiding deleterious side effects which would be expected due to the ubiquitous expression of the glucose transporter in many tissues and organs. Applicant argues that one could predict side effects based on general medical knowledge. Applicant is invited to provide evidence of general medical knowledge of management of the pleiotrophic side effects of inhibition of this ubiquitous transporter protein.

Applicants arguments are unconvincing, and the rejection is maintained.

Claim Rejections - 35 USC § 102

Claim 30 remains rejected under 35 U.S.C. 102(b) as anticipated by Palker et al (Journal of Virological Methods 18:243-255, 1987). Claim 30 has been amend to require that the polypeptide corresponds to envelope proteins of PTLV or fragments or derivatives that specifically bind to SEQ ID NO:2. The required ability to bind is an inherent characteristic of the gp46 protein of HTLV-1. Applicant argues that, since HTLV envelope can bind to other factors, it does not "specifically bind" to GLUT1. This is not consistent with the usage of the term in the specification, see for example page 1, lines 22-24, which refers to "specific binding" of HTLV envelope to GLUT1. It is maintained that the claim, as written, reads upon the purified gp46 of Palker, and is therefore anticipated by the reference.

Allowable Subject Matter

The following claims are suggested, as allowable subject matter:

32. A method for in vitro diagnosis of pathologies linked to over-expression of GLUT1 on cell surfaces, said method comprising:

- contacting a biological sample from an individual with a GLUT1 binding polypeptide, said GLUT1 binding polypeptide being optionally labeled, or susceptible to be recognized by a labeled molecule, wherein said GLUT1 binding polypeptide comprises an envelope protein of a primate T-cell leukemia virus (PTLV), or a fragment thereof, that specifically binds to the ubiquitous vertebrate glucose transporter GLUT1 represented by SEQ ID NO: 2;

and

- determining the level of said GLUT1 binding polypeptide bound to cells contained in the biological sample and comparing with the level of binding of said GLUT1 binding polypeptide to cells contained in a biological sample from a healthy individual,

wherein an elevated level of binding indicates a pathology linked to overexpression of GLUT-1.

33. The method of claim 33, wherein the GLUT1 binding polypeptide is able to bind to at least one of the following fragments of GLUT1 selected from the group consisting of:

- SEQ ID NO: 25: NAPQKVIEEFY;

- SEQ ID NO: 26: NQTWVHRYGESILPTTLTTLWS;

- SEQ ID NO: 27: KSFEMLILGR;

- SEQ ID NO: 28: DSIMGNKDL;

- SEQ ID NO: 29: YSTSIFEKAGVQQP;

- SEQ ID NO: 30: EQLPWMSYLS;

- SEQ ID NO: 31: QYVEQLC; and

- SEQ ID NO: 32: IVGMCFQYVEQLC.

34. The method of claim 33, wherein the GLUT1 binding polypeptide is able to bind to at least the following fragment of GLUT1:

- SEQ ID NO: 32: IVGMCFQYVEQLC

35. The method of claim 33, wherein the GLUT1 binding polypeptide is selected from the group consisting of:

- the envelope protein of HTLV-I,

- the envelope protein of HTLV-2,

- the envelope protein of STLV-1,

- the envelope protein of STLV-2, and

- the envelope protein of STLV-3.

36. The method of claim 35, wherein the GLUT-1 binding polypeptide is selected from the group consisting of SEQ ID NO: 4, 6, 8, 10, and 12.

37. The method of claim 33, wherein the GLUT-1 binding polypeptide is a fragment of a PTLV envelope protein, wherein the fragment has its N- terminal located between positions 1 to 90 and its C-terminal located between positions 135 to 245 of the sequence of said PTLV envelope protein.

38. The method of claim 37, wherein said fragment has its N- terminal located between positions 75 to 90 and its C-terminal located between positions 135 to 150 of the sequence of said PTLV envelope protein.

39. The method of claim 37, wherein the PTLV envelope protein sequence is selected from the group consisting of SEQ ID NO: 4, 6, 8, 10, and 12.

40. The method of claim 37, wherein the PTLV envelope protein sequence is the HTLV-1 MT-2 strain sequence SEQ ID NO:4, and the fragment has its N-terminal located between positions 83 to 89, and its C-terminal located between positions 139 to 145.

41. The method of claim 37, wherein the PTLV envelope protein sequence is the HTLV-2 sequence SEQ ID NO:6, and the fragment has its N-terminal located between positions 79 to 85, and its C-terminal located between positions 135 to 141.

42. The method of claim 37, wherein the PTLV envelope protein sequence is the STLV-1 sequence SEQ ID NO:8, and the fragment has its N-terminal located between positions 83 to 89, and its C-terminal located between positions 139 to 145.

43. The method of claim 37, wherein the PTLV envelope protein sequence is the STLV-2 sequence SEQ ID NO:10, and the fragment has its N-terminal located between positions 79 to 85, and its C-terminal located between positions 135 to 141.

44. The method of claim 37, wherein the PTLV envelope protein sequence is the STLV-2 sequence SEQ ID NO:12, and the fragment has its N-terminal located between positions 82 to 88, and its C-terminal located between positions 138 to 144.

45. A method for in vitro diagnosis of pathologies linked to over-expression of GLUT1 on cell surfaces, said method comprising:

- contacting a biological sample from an individual with a GLUT1 binding polypeptide selected from the group consisting of SEQ ID NO: 14, 16, 18, 20, 22, and 24, said GLUT1 binding polypeptide being optionally labeled, or susceptible to be recognized by a labeled molecule, and

- determining the level of said GLUT1 binding polypeptide bound to cells contained in the biological sample and comparing with the level of binding of said GLUT1 binding polypeptide to cells contained in a biological sample from a healthy individual,

wherein an elevated level of binding indicates a pathology linked to overexpression of GLUT-1.

Claim 32 is suggested as an allowable replacement for claim 16; it contains language relating the measurement to the purpose recited in the preamble, and more clearly defines the invention. Claims 33-34 replace claims 17 and 18. Claims 35-45 more clearly state the subject matter of claim 19. Claims 35 and 36 specify the species of HTLV envelope protein. Claims 37-38 specify a range of boundaries of envelope

protein fragments from generic primate TLVs,, and claims 39-44 further limit the fragments to specific sequences. Claim 45 recites functional variants of env protein sequences which are fully described in the specification.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

5/22/09